REMARKS

After the present amendment, claims 1-6 and 8-29 are pending. All pending claims have been rejected in the outstanding Office Action.

AMENDMENTS

The specification has been amended amend the paragraph at page 13, lines 1-7 to avoid confusion at the range including a negative number as helpfully suggested by the Examiner.

Claim 1 has been amended to insert the term wherein a suspension of the polymeric microcapsules is formed within one minute of mixing the surfactant phase with the drug phase, as helpfully suggested by the Examiner. This amendment finds support in the specification at page 13, lines 13-15

Claim 4 has been amended to remove the term "at least" from the claim.
Claim 14 has been amended to replace the term "drug solution" with --drug phase--.
Claim 22 has been amended to remove "thereof" from the claim as an obvious oversight from a previous amendment.

It is respectfully submitted that the present amendments do not introduce new matter.

Claim 30 has been cancelled without prejudice to expedite prosecution.

Specification Objections

The use of trademarks as they appear in the present specification has been objected to. It is respectfully submitted that the trademark usage is proper in the context of the specification. The objective of the US Patent Office is to assure that the proprietary nature of trademarks are respected. In the present application, all marks are clearly indicated to be trademarks by use of the ® symbol, and additionally the generic description for each product is associated with the mark.

The description at page 13, line 6 has been amended as helpfully suggested by the Examiner.

Double Patenting

Claims 1-6, 8-17, 20-30 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6,899,898.

In order to expedite prosecution, a terminal disclaimer of the present application in view of the cited patent is enclosed herewith. This terminal disclaimer is submitted without prejudice to presentation of arguments of separate patentability at a later date and/or different forum if necessary.

Claim Rejections 35 U.S.C. 112

Claims 4, 14 and 23 have been rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

More specifically, the range of claim 4 has been objected to as being unclear. This claim has been amended to remove the combination of terms "at least" and a range in order to avoid confusion. It is respectfully submitted that the claim now describes a range in the conventional manner, and the claim scope thus can be appropriately determined in accordance with conventional principles of claim construction.

Claim Rejections 35 U.S.C. 103

Claims 1-6, 8-17, 20-30 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Rössling et al (WO 97/19676).

Claims 18-19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Rössling et al. as applied to claims 1-17 and 20-30 above, and further in view of Setterstrom et al (6,410,056).

The present invention relates to a process for the production of polymeric microparticles comprising dissolving a polymer in a selected, halogen-free solvent, said solvent being at least partially water-miscible, to form a polymer solution. A hydrophilic active agent is added to the polymer solution to form a drug phase contained in a vessel.

A predetermined amount of an aqueous surfactant phase is added to the vessel containing the drug phase with mixing, wherein the volume fraction of the surfactant phase is at least 0.60 and wherein $\delta_{\text{polymer solvent}} - \delta_{\text{aqueous phase}} < 0$. The predetermined amount is sufficient to provide that the surfactant phase becomes the continuous phase and extraction medium in order to extract an amount of the solvent from the drug phase such that a suspension of microparticles is produced upon addition of the surfactant phase to the drug phase without the formation of an intermediate W/O/W double emulsion and without requiring removal of solvent from the vessel. This suspension of the polymeric microcapsules is formed within one minute of mixing the surfactant phase with the drug phase.

Rössling describes a method of making microcapsules wherein a polymer is dissolved in a halogen-free solvent or solvent mixture that is not water-miscible or is partially water-miscible, and a buffered active ingredient solution having a pH of between 6.0-8.0 is dispersed in this solution. The solution is homogenized, producing a stable W/O-emulsion. An aqueous solution that contains a surfactant or a mixture of surfactants is added to this W/O-emulsion as an outer phase while being stirred, in such a way that a three-phase W/O/W emulsion is obtained. Then, the solvent or solvent mixture is removed with commonly used methods, preferably in a vacuum and/or air/nitrogen stream. See the English language US Patent (6,294,204) at column 3, lines 60-67.

Thus, expressly taught steps in the Rössling reference, the formation of an intermediate W/O/W double emulsion and removal of solvent from the vessel, are expressly excluded from the present claims. The presently claimed process is therefore not a mere optimization of known parameters in a prior art process, but rather is a change "in kind" (rather than degree) from the process as a whole taught in the prior art. The skilled artisan would have had no motivation to modify the prior art process to exclude steps that are expressly taught in the prior art.

Setterstrom is cited for the purpose of teaching regarding microspheres, microcapsules and microsponges. It is respectfully submitted that Setterstrom does not bridge the gap between Rössling and the present claims, because it fails to teach or suggest modification of a process for the production of polymeric microparticles to eliminate the steps of formation of an intermediate W/O/W double emulsion and removal

of solvent from the vessel. Absent a teaching or suggestion to modify the process to eliminate these steps, the present process is unobvious.

Further, the claims have been amended as helpfully suggested by the Examiner to now require that "a suspension of the polymeric microcapsules is formed within one minute of mixing the surfactant phase with the drug phase." It is respectfully submitted that the cited references fail to meet or suggest this requirement, and that the claims as amended are not obvious in view of the cited prior art.

CONCLUSION

It is respectfully submitted that all of the pending claims are in condition for allowance, and respectfully request notification thereof. In the event that a phone conference between the Examiner and the Applicants' undersigned attorney would help resolve any remaining issues in the application, the Examiner is invited to contact the attorney at (651) 275-9811.

Dated: May 15, 2006

Respectfully submitted,

By: _____
Dale A. Bjorkman
Reg. No. 33084
Phone: 651-275-9811
Fax: 651-351-2954

25670